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IN THE

Supreme Court of the United States

October Term, 1976
No.

ELIZABETH DALEY, M.D.,

Petitioner,

-against-

F. DAVID MATHEWS, Secretary of Health, Education and Welfare, ALEXANDER M. SCHMIDT, M.D., Commissioner of Food and Drugs, CLIFFORD G. SHANE, Regional Director of the Food and Drug Administration, TERRY MUSSON, ALLEN R. HALPER, JOHN E. KLEMMER and THOMAS D. GARDINE, Employees of the Food and Drug Administration,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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ELIZABETH DALEY, M.D.,

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Respondents.

PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

The petitioner, Elizabeth Daley, M.D., respectfully requests that a writ of certiorari issue to review the judgment and opinion of the United States Court of Appeals for the Second Circuit entered in this proceeding on May 27, 1976.

OPINIONS BELOW

The opinion of the Court of Appeals is reported at 536 F.2d 519 and appears in the Appendix hereto, p. 1a. The memorandum and order of the District Court for the Eastern District of New York is reported at 400 F.Supp. 1288 and appears in the Appendix hereto, p. 7a.

JURISDICTION

The judgment of the Court of Appeals for the Second Circuit was entered on May 27, 1976. A timely petition for rehearing was denied on July 20, 1976. Jurisdiction of this Court is invoked under 28 U.S.C. §1254(1).

QUESTIONS PRESENTED

1. Did a controversy sufficiently ripe for adjudication exist between petitioner and the Federal Food and Drug Administration following petitioner's refusal, for the second time in less than three weeks, to permit federal inspectors who had served notices of

inspection pursuant to 21 U.S.C. §374(a) to enter her medical office for the purpose of conducting a warrantless administrative inspection?

2. Does 21 U.S.C. §374(a) authorize a warrantless administrative inspection of the medical office of a licensed physician, where drugs present in the physician's office consist entirely of federally approved drugs or combinations thereof prepared by the physician for use solely in the course of her professional practice?

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

U.S. Constitution, Article III, Section 3

> [1] The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority;--to all Cases affecting Ambassadors, other public Ministers and Consuls;--to all Cases of admiralty and maritime Jurisdiction;--to Controversies to which the United States shall be a Party;--to Controversies between two or more States;--between Citizens of different States;--between Citizens of the same State claiming Lands under Grants of different States, and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects.

U.S. Constitution, Amendment IV

> The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.

21 U.S.C. §331

Prohibited acts

The following acts and the causing thereof are prohibited:

* * *

(f) The refusal to permit entry or inspection as authorized by section 374 of this title.

21 U.S.C. §333

Penalties--Violation of section 331 of this title

(a) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

21 U.S.C. §374

Inspection--Right of agents to enter; scope of inspection; notice; promptness; exclusions

(a) For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the

owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any * * * establishment in which * * * drugs * * * are manufactured, processed, packed, or held, for introduction into interstate commerce * * * and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such * * * establishment * * * and all pertinent equipment, finished and unfinished materials; containers, and labeling therein. In the case of any * * * establishment * * * in which prescription drugs are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter. * * * The provisions of the second sentence of this subsection shall not apply to--

* * * * *

(2) practitioners licensed by law to prescribe or administer

drugs and who manufacture, prepare, propagate, compound, or process drugs solely for use in the course of their professional practice * * *.

28 U.S.C. §2201

Creation of remedy

In a case of actual controversy within its jurisdiction, except with respect to Federal taxes, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

STATEMENT OF THE CASE

On February 28, 1975, immediately following a second attempt by Food and Drug Administration ("FDA") inspectors to enter and inspect her medical

office, petitioner, Elizabeth Daley, M.D., a licensed physician, brought this action under 28 U.S.C. §§1331 and 1337 seeking a declaratory judgment that the FDA lacks jurisdiction to investigate, inspect or otherwise enforce the provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. §§301, et seq., against a state-licensed physician engaged in the lawful practice of medicine, and further seeking injunctive relief against such investigation, inspection or enforcement. Named as respondents were the Secretary of Health, Education and Welfare and the Commissioner, Regional Director and four employees of the FDA.

In a memorandum and order dated

October 2, 1975, the District Court for the Eastern District of New York granted summary judgment to respondents and dismissed the complaint on the ground that a controversy sufficiently ripe for adjudication did not exist between the parties. The Court of Appeals for the Second Circuit affirmed. Neither the District Court nor the Court of Appeals considered the merits of petitioner's contention that the FDA lacked statutory authority to conduct a warrantless inspection of her medical office.

Petitioner is a licensed physician who suffers from rheumatoid arthritis and who for many years has specialized in the treatment of this disease.

The principal method of treatment employed by petitioner is based upon three hormones--prednisone, testosterone and estradiol--which are administered to patients in varying combinations and dosages. This form of treatment was originally developed by the late Dr. Robert Liefmann, a Canadian physician, and the various hormonal combinations came to be loosely referred to as "Liefcort." While prednisone, testosterone and estradiol are well-known, federally-approved drugs, "Liefcort" does not accurately refer to any specific drug or chemical formulation.

On February 10, 1975, an FDA inspector appeared at petitioner's New York City medical office for the purpose

of conducting an administrative inspection pursuant to Section 704 of the Food, Drug and Cosmetic Act, 21 U.S.C. §374 (hereafter "Section 704"). Petitioner was not present at the time, and the inspector served an official Notice of Inspection upon petitioner's nurse.* The nurse did not permit the inspection and declined to answer any questions concerning petitioner's medical practice, except to inform the inspector of petitioner's office hours and refer him to petitioner's attorneys.

Thereafter, petitioner's attorney was in contact with the Regional

*A copy of the Notice appears in the Appendix infra, p. 32a.

Office of the FDA. He was informed that the FDA was investigating alleged use by petitioner of an unapproved drug known as "Liefcort." On February 24, petitioner's attorney formally requested, in writing, the basis of the FDA's jurisdiction to investigate the manner in which petitioner prescribed medication and treated patients in the course of her medical practice.

On February 25, in response to this request, a Supervisory Consumer Safety Officer of the FDA telephoned petitioner's attorney and advised him that the FDA was investigating petitioner's alleged use of "Liefcort." The attorney informed the FDA official that

petitioner was not receiving or distributing "Liefcort," but was prescribing the hormones prednisone, testosterone and estradiol for her patients. He further advised the FDA that petitioner would not permit an inspection of her medical office or submit to interrogation by FDA inspectors, but that she would voluntarily provide any information the FDA requested concerning medications used in her practice.

Two days after this conversation, on February 27, two FDA inspectors went to petitioner's office and served a second Notice of Inspection. They were not permitted to enter or inspect the office.

The following day, February 28, this action was commenced seeking declaratory and injunctive relief against investigation, inspection or other enforcement of the provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. §§301, et seq., against petitioner for conduct consisting of "preparing, prescribing and administering approved drugs or combinations thereof to [her] own patients in the course of [her] own medical practice." (App., infra, p. 29a).*

The complaint alleges, inter alia, that:

1. The drugs prescribed by

*The amended complaint appears in the Appendix, infra, p. 22a.

petitioner in the course of her medical practice are all fully approved under federal law, and her conduct in preparing, prescribing and administering approved drugs and combinations thereof to her own patients is her lawful right and professional prerogative as a licensed medical practitioner.

2. Petitioner offered to fully disclose and openly discuss with FDA officials, through her attorney, all relevant details concerning the medications she prescribes to her patients, but that the FDA declined this offer, and as a result a controversy continues to exist which requires petitioner to function under a constant threat of impending action

against her by the federal government.

3. Under the circumstances as alleged, the FDA lacks authority, pursuant to the Food, Drug and Cosmetic Act, 21 U.S.C. §§301, et seq., to investigate, inspect or otherwise interfere with petitioner's medical practice.

4. The conduct of the FDA in investigating, inspecting, threatening to do the same, or otherwise interfering with petitioner's right to practice her profession, is violative of the Fourth, Fifth and Sixth Amendments of the Constitution, the Food, Drug and Cosmetic Act, and the physician-patient privilege.

5. The conduct of the FDA is causing petitioner and her patients

irreparable injury in that she is being deprived the Fourth Amendment right to be free from unreasonable search and seizure and the Fifth Amendment right to practice her profession, that continued investigation by the FDA will destroy her professional reputation and prevent her patients from receiving treatment, that she is being unlawfully subjected to possible criminal prosecution and resulting fine, imprisonment and loss of her license to practice medicine for refusal to permit inspection of her office and/or other violation of the Food, Drug and Cosmetic Act, 21 U.S.C. §331.

Petitioner also moved for a temporary restraining order against further

FDA action against her, in support of which she submitted an affidavit which stated, in part:

> For several years my medical practice has concentrated on rheumatoid arthritis and other rheumatic diseases. The method of treatment which I employ is based upon special diet and the administration of various medications. These medications include the hormones prednisone, testosterone and estradiol which are administered in varying dosages according to the particular requirements of the individual patient. This method of treatment has proven to be successful with thousands of patients over a period of many years.
>
> I myself have a serious rheumatoid arthritis condition which is treated with these medications. It is because of this treatment that I am able to continue to function as an active medical practitioner.
>
> * * *
>
> Any medications which are prepared at my office are used solely in the treatment of my own patients as prescribed by

me and my colleague, Dr. Henry Rosenberg. Further, any such medications are composed entirely of legally and medically approved drugs.

It is my understanding, and I again have recently been so advised by my attorney, that it is completely lawful for a licensed physician to prepare, prescribe and administer medications in the manner in which I have been so doing.

I cannot overemphasize the efficacy of the method of treatment which I employ. It is effective in treating rheumatic disease. To deny this medication and treatment to the thousands of patients that are now using it successfully would result in needless suffering and crippling. This would be an outrageously inhumane act.

My medical practice cannot be conducted under a constant threat of unlawful intrusion by federal inspectors to say nothing of the harm to my professional reputation which results therefrom.

The present situation is intolerable and must be resolved as expeditiously as possible. It is for this reason that I urge

the Court to prohibit the Food and Drug Administration from taking any further action in this matter pending final resolution of this controversy.

(A-15-17)*

The application for a temporary restraining order was thereafter withdrawn upon the government's stipulation that no further action would be taken against petitioner except upon notice in the pending action.

Respondents then filed a motion to dismiss or in the alternative for summary judgment, essentially claiming that the action is an unconsented suit against the United States barred under the doctrine

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*Page references preceded by the letter "A-" refer to Appellant's Appendix, a separate volume filed in the Court of Appeals.

of sovereign immunity; that the FDA does have statutory authority to investigate and inspect petitioner's medical office; that no justiciable controversy exists between the parties; and that there is no basis for injunctive relief (A-18-20).

In support of their motion respondents submitted an affidavit of Paul J. Sage, who, as Assistant to the Director of Regulatory Operations of the Bureau of Drugs of the FDA, authorized the investigation and inspection of petitioner (A-38). Also submitted were affidavits of respondent Terry Musson, Supervisory Safety Officer for the FDA, who issued the actual orders to inspect petitioner's office (A-22); respondent Allen

R. Halper, who served the Notice of Inspection on February 7, 1975 (A-25); and respondent John E. Klemmer, who, with respondent Thomas D. Gardine, served the Notice of Inspection of February 27, 1975 (A-28).

Respondents also submitted an affidavit of George J. Gerstenberg, Deputy Regional Director of the New York District of the FDA. The affidavit states that the FDA had received

> . . . a report that Liefcort, a new drug for which no approved New Drug Application is in effect, had been received after shipment in interstate commerce by Dr. Elizabeth Daley and Dr. Henry Rosenberg at their office at 320 West End Avenue, New York, New York, and was being used for the treatment of patients.

(A-30).

Prior to submitting papers in opposition to respondents' motion for dismissal and summary judgment, petitioner requested discovery concerning the basis of the FDA's belief that she was receiving or distributing "Liefcort" or any other "hazardous drugs." Respondents moved for a protective order, claiming the requested information was irrelevant, and stating:

> The crucial and only issue before the Court is the authority of officers or employees of the Food and Drug Administration to enter, after the presentation of their credentials and written notice, into the premises of the plaintiffs herein for the purposes of making an inspection pursuant to 21 U.S.C. 374.

(Memorandum of Law in Support of Defendants' Motion for Protective Order, p. 2)

The district court ruled that

respondents' motion for a protective order be held in abeyance pending possible resolution of the essentially legal question of the construction of Section 704.

In opposition to respondents' motion for dismissal and summary judgment petitioner argued that on the basis of the express statutory exemptions in the Food, Drug and Cosmetic Act, its legislative history, official published statements of the FDA Commissioner, judicial interpretation, and writings of experts in the field of food and drug law, the FDA lacks authority to regulate a licensed physician's use of federally-approved drugs or combinations thereof in the

treatment of his own patients. It was further argued that Section 704 expressly exempts licensed physicians from FDA inspection, and also that since the FDA lacks underlying regulatory authority of physicians, respondents' construction of Section 704 is violative of the Fourth Amendment. (Memorandum of Law in Opposition to Defendants' Motion To Dismiss and For Summary Judgment, pp. 7-22).

On July 11, 1975, after hearing oral argument of respondents' motion, the district court attempted to resolve the controversy by suggesting that the parties arrange for a voluntary inspection of petitioner's office, at which counsel would be present. Petitioner agreed. Respond-

ents, who were represented by government counsel as well as a representative from FDA headquarters in Maryland, refused (A-45-51).

Thereafter, in a memorandum and order dated October 2, 1975, the district court granted respondents' motion for summary judgment and dismissed the complaint on the ground that the controversy was not sufficiently ripe for adjudication. The Court of Appeals affirmed.

REASONS FOR GRANTING THE WRIT

I.

THE COURT BELOW HAS MISAPPLIED THE RIPENESS STANDARD ESTABLISHED BY THIS COURT.

The controversy existing between

petitioner and respondents is clearly defined. Respondents contend they have the authority, pursuant to Section 704 of the Food and Drug Act (21 U.S.C. §374), to conduct an administrative inspection of petitioner's medical office. The record amply demonstrates that respondents fully intended to exercise this purported authority against petitioner, and did in fact exercise it prior to commencement of this action for declaratory and injunctive relief.

It is petitioner's position that as a state-licensed medical practitioner who prepares and prescribes medications consisting entirely of federally-approved component drugs, solely for use

of her own patients, she does not fall within the regulatory authority of the FDA. Specifically, she contends that Section 704 does not authorize a warrantless, administrative search of her office.

This action was commenced only after the FDA refused to attempt to conduct its investigation of the drug "Liefcort" with petitioner's cooperation, in some reasonable manner other than by inspection of her office. During pendency of the action in the district court petitioner eventually agreed to permit the FDA to inspect the office, provided only that the date and time be prearranged so that counsel could be present. This also was refused.

It cannot seriously be questioned that under these circumstances an actual controversy, based upon a concrete set of facts, exists between the parties. This is certainly not the case of a litigant seeking an advisory opinion; the judgment requested here will have a very real impact upon the parties--it will either permit or prohibit FDA inspection of petitioner's office.

In dismissing the complaint the district court held that this controversy was not sufficiently ripe for adjudication. Applying the test of Abbott Laboratories v. Gardner, 387 U.S. 136 (1967), the court wrote:

> While the issue raised appears to be a purely legal one, i.e., the FDA's statutory authority to inspect a physician's office, there is here no final agency action whose legality the court may pass upon. Although FDA agents made two visits to plaintiff's office, no inspection was in fact conducted. The court is reluctant to anticipate what future action, if any, FDA may decide to take.

(App., infra, p. 12a)

In affirming, the court of appeals similarly stated:

> The FDA has declined to take any affirmative action which could ripen the controversy for judicial review. It is thus impossible to predict whether the agency will attempt another inspection, whether it will seek to obtain an injunction under 21 U.S.C. Section 332 or an inspection warrant upon a showing of probable cause compelling Dr. Daley to permit inspection, whether it will institute criminal proceedings against the Doctor under 21 U.S.C. Sections 331(f) and 333(a), whether it will eventually accede to Dr. Daley's offer of an inspection with counsel present or whether it will simply do nothing. . . .

(App., infra, p. 5a)

We contend that the ripeness standard has been misapplied. The courts below have misconstrued the concept of "final agency action" and failed to accord sufficient weight to the dilemma facing petitioner.

In Abbott Laboratories v. Gardner, supra, after noting that "judicial review of a final agency action by an aggrieved person will not be cut off unless there is a persuasive reason to believe that such was the purpose of Congress," 387 U.S. at 140, the Court set forth the basic guidelines for determining ripeness:

> Without undertaking to survey

> the intricacies of the ripeness doctrine it is fair to say that its basic rationale is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties. The problem is best seen in a twofold aspect, requiring us to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court decision.

387 U.S. at 148-149 (footnote omitted).

Thus the first prong of the test concerns fitness of the issues for judicial resolution. In Abbott, the Court initially noted that the issues were appropriate for judicial decision because "all parties agree that the issue tendered is a purely legal one: whether

the statute was properly construed by the Commissioner . . . ." 387 U.S. at 149. This, of course, is precisely the situation here.* If anything, this case presents an a fortiori situation since only federal statutes rather than administrative regulations are involved, and the question of statutory construction is particularly well suited for judicial examination. See Aquavella v. Richardson, 437 F.2d 397, 404 (2d Cir. 1971).

The next factor emphasized in Abbott was that the agency action under

*Indeed, in opposing petitioner's request for discovery in the district court, respondents argued that "[t]he only issue before the Court is the statutory provisions relating to the administrative inspection." (Memorandum of Law in Support of Motion for Protective Order, p. 5).

review was final under the "pragmatic" and "flexible" test established in prior cases. 387 U.S. at 149-152.

Agency action takes many forms.* Frequently, the action challenged in a pre-enforcement lawsuit consists of a regulation or order which is claimed to be in excess of staturory authority. See, e.g., Abbott Laboratories v. Gardner, supra (FDA regulation); Columbia Broadcasting v. United States, 316 U.S. 407 (1942) (FCC regulation); Frozen Food Express v. United States, 351 U.S. 40 (1956)

*For example, under the Administrative Procedure Act, 5 U.S.C. 551(13), "agency action" includes "the whole or a part of any agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act."

(ICC order). But obviously, other forms of agency action not involving regulations or published orders are subject to judicial review. See, e.g., National Automatic Laundry and Cleaning Council v. Schultz, 443 F.2d 689 (D.C. Cir. 1971) (Letter of Wage-Hour Administrator interpreting provision of the Fair Labor Standards Act held to be final agency action and reviewable); Independent Broker-Dealers' Trade Association v. Securities & Exchange Comm., 442 F.2d 132 (D.C. Cir. 1971) (Letters of SEC Commissioner to New York Stock Exchange which led to stock exchange abandonment of customer directed "give-ups" held to be reviewable agency action).

In the present case, the agency

action consists of the FDA's interpretation of Section 704 of the Food and Drug Act, and its attempt, on two separate occasions, to enter and inspect petitioner's office pursuant thereto. Under the "pragmatic" and "flexible" test of Abbott Laboratories v. Gardner, supra, this was final agency action.

The initial order to inspect petitioner's office was hardly a low level administrative decision. The investigation and inspection were ordered by Paul J. Sage, Assistant to the Director of the Division of Regulatory Operation of the FDA Bureau of Drugs (A-39).

After petitioner's refusal to permit this inspection, a period of

negotiations ensued, during which her attorney challenged the FDA's authority, but also expressed her willingness to cooperate in some manner other than inspection. The FDA's response was to serve a second Notice of Inspection. Certainly we may properly assume that the decision to pursue that course, rather than accept petitioner's offer of cooperation, was a considered judgment of the agency.

Furthermore, throughout this litigation, the FDA has steadfastly maintained its interpretation of Section 704. At oral argument of respondents' motion for dismissal and summary judgment, petitioner agreed to permit FDA inspectors

to enter her office and examine her medications, provided only that the date and time be prearranged so that counsel could be present. The FDA, which was represented by government counsel as well as its own representative from Maryland headquarters, refused (A-45-51).

In view of this record, the construction of Section 704 presently urged by respondents is certainly a "considered and formalized determination" of the FDA. Toilet Goods Association v. Gardner, 387 U.S. 158, 162 (1967). As such, it is judicially reviewable, final agency action.

The second prong of the Abbott test concerns hardship to the parties of

withholding judicial relief.

Prior to the commencement of this lawsuit, petitioner had twice refused to permit FDA inspection of her office pursuant to 21 U.S.C. §374. 21 U.S.C. §331, which is entitled "Prohibited acts," provides in pertinent part:

> The following acts and the causing thereof are prohibited:
>
> * * *
>
> (f) The refusal to permit entry or inspection as authorized by section 374 of this title.

21 U.S.C. §333 further provides:

> (a) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

Thus petitioner faces criminal prosecution and possible fine and/or

imprisonment for refusing these inspections. While it is obviously not possible to determine whether the government will actually bring such an enforcement proceeding against petitioner, this Court has held that the possibility of such action is sufficient to warrant review.

In Gardner v. Toilet Goods Association, 387 U.S. 167, 172 (1967), where cosmetics manufacturers were permitted pre-enforcement review of regulations which imposed possible criminal sanctions, the Court wrote:

> Faced with these regulations the respondents are placed in a quandary. On the one hand they can, as the Government suggests, refuse to comply, continue to distribute products that they believe do not fall within the purview of the Act, and test the regulations by

> defending against government criminal, seizure, or injunctive suits against them. We agree with respondents that this proposed avenue of review is beset with penalties and other impediments rendering it inadequate a satisfactory alternative to the present declaratory judgment action.

Similarly, in Doe v. Bolton, 410 U.S. 179, 188 (1973), the Court permitted the physician-appellants to obtain declaratory relief against the Georgia abortion statutes though none of them had even been threatened with prosecution:

> [T]he physician-appellants, who are Georgia-licensed doctors consulted by pregnant women, also present a justiciable controversy and do have standing despite the fact that the record does not disclose that any one of them has been prosecuted, or threatened with prosecution, for violation of the State's abortion statutes. The physician is the one against whom these criminal statutes directly operate in the event he procures an abortion that does

> not meet the statutory exceptions and conditions. The physician-appellants, therefore, assert a sufficiently direct threat of personal detriment. They should not be required to await and undergo a criminal prosecution as the sole means of seeking relief. . . .

The reasoning of both cases applies here a fortiori. For in the present case, petitioner faces possible prosecution for acts already committed (i.e., refusal to permit inspection of her medical office on two occasions). Moreover, in the present case, declaratory judgment is the only means for petitioner to test her interpretation of the statute in question without risking criminal sanctions.*

*It should be noted that 21 U.S.C. §335, which provides an opportunity for a hearing prior to commencement of criminal enforcement proceedings, has been held not

Even if the FDA chose to proceed civilly against petitioner under 21 U.S.C. §332 to compel compliance with Section 704, such a proceeding would be most injurious to her reputation in the sensitive medical profession. (Compare Abbott Laboratories v. Gardner, supra, 387 U.S. at 153, where the Court emphasized the sensitivity of the drug industry).

Furthermore, the hardship to petitioner of withholding judicial review is not limited to the consequences of possible enforcement proceedings. As petitioner emphasized in her affidavit sub-

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to be a prerequisite for prosecution. United States v. Dotterweich, 320 U.S. 277 (1943).

mitted in support of injunctive relief:

> My medical practice cannot be conducted under a constant threat of unlawful intrusion by federal inspectors to say nothing of the harm to my professional reputation which results therefrom.
>
> The present situation is intolerable . . . .

(A-17).

There appears to be no justification for permitting a situation to continue whereby petitioner is left in a permanent state of uncertainty, not knowing when FDA inspectors will next appear at her office door, or when the agency will seek civil or criminal sanctions against her. With no alternative remedy available to her, she will be left helplessly and indefinitely at the mercy of

the FDA unless afforded judicial relief.

II.

THE DECISION BELOW PERMITS A FEDERAL AGENCY TO EVADE JUDICIAL REVIEW BY TEMPORARILY SUSPENDING CHALLENGED ADMINISTRATIVE ACTION WHENEVER AN AGGRIEVED PARTY SEEKS JUDICIAL RELIEF.

A fundamental issue raised in this petition is whether a federal agency may effectively insulate itself from judicial review by simply "retreating" whenever a citizen against whom it has taken unlawful administrative action seeks to challenge the agency's authority in federal court, thereby eliminating the jurisdictional prerequisite of an actual case or controversy. This is precisely what

occurred here and was unfortunately condoned by the Court below.

In affirming dismissal of the complaint for lack of ripeness the court of appeals viewed this case as a "pre-enforcement" challenge to agency action.*

*In its opinion the court wrote:

> In a trilogy of decisions . . . . the Supreme Court made clear that in assessing the fitness for review of challenges to pre-enforcement agency action . . . .

and,

> Seemingly, [petitioner's] situation is more closely analagous to that in Toilet Goods Assn., Inc. v. Gardner, supra, where the Court found that "consideration of the underlying legal issues would necessarily be facilitated if they were raised in the context of a specific attempt to enforce the regulations." 387 U.S. at 171 [footnote omitted].

(App., infra, p. 6a) (emphasis added).

If that were correct, that is, if the FDA had never attempted to enforce the challenged statute--Section 704 of the Food and Drug Act--against petitioner, then she would have little cause to complain. But that is simply not the case.

FDA inspectors first served a notice of inspection and attempted to search petitioner's medical office on February 10, 1975. They were refused entry and referred to petitioner's attorneys. For approximately two weeks thereafter, there were several communications between petitioner's counsel and FDA officials, during which petitioner offered to cooperate with the FDA (in their apparent investigation of drugs she was administer-

ing to her patients) in any reasonable manner other than through an unauthorized "factory inspection" of her medical office. FDA's ultimate response was to reject this offer, and to serve a second notice and attempt another inspection on February 27. Of course, respondents knew full well, having spoken to petitioner's lawyer just two days prior, that they would again be denied entry to petitioner's office for purposes of such an inspection. The very next day, February 28, severely shaken by what had already occurred and fearing what further action the FDA might take against her, petitioner commenced this lawsuit for declaratory and injunctive relief.

It is thus quite clear that this case does not present a "pre-enforcement" situation. This action was filed only after the FDA not once, but twice, attempted to enforce the factory inspection statute [21 U.S.C. §374(a)] against petitioner. A ripe controversy existed at that time, and subsequent representations or temporary withdrawal by the FDA should not be permitted to defeat it.

In Abbott Laboratories v. Gardner, 387 U.S. 136 (1967), where drug manufacturers challenged FDA regulations, a somewhat similar situation arose. There, as here, non-compliance with the challenged enactment carried criminal sanctions, but the government represented

that no criminal prosecution would be brought.* In holding the controversy ripe for adjudication, the Court said:

> The Government further contends that the threat of criminal sanctions for noncompliance with a judicially untested regulation is unrealistic; the Solicitor General has represented that if the court enforcement becomes necessary, "The Department of Justice will proceed only civilly for an injunction . . . or by condemnation." We cannot accept this argument as a sufficient answer to petitioners' petition. This action at its inception was properly brought and this subsequent representation of the Department of Justice should not suffice to defeat it.

327 U.S. at 154.

*No such representation has been made in the present case. However, in a post-argument letter to the court of appeals dated April 23, 1976, the government indicated that it did not at that time intend to criminally prosecute petitioner for refusing the two attempted inspections.

Similarly, the government should not be permitted to unilaterally defeat petitioner's right to judicial relief in the present case.

III.

SECTION 704(a) OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT, 21 U.S.C. §374(a), DOES NOT AUTHORIZE WARRANTLESS ADMINISTRATIVE INSPECTION OF THE MEDICAL OFFICE OF A LICENSED MEDICAL PRACTITIONER WHO PRESCRIBES, PREPARES AND ADMINISTERS MEDICATIONS CONSISTING OF COMBINATIONS OF FEDERALLY APPROVED DRUGS SOLELY IN THE COURSE OF HIS PROFESSIONAL PRACTICE.

The basis of the FDA's investigation of petitioner is her alleged use of "Liefcort," an unapproved "new" drug (A-30-31). The inspections were ordered essentially to determine if this drug was

present at plaintiff's medical office (A-39).

Although not completely accurate, it can be assumed, for sake of argument, that "Liefcort" is equivalent to a combination of the three hormones prednisone, testosterone and estradiol, each of which is federally approved.

Under the Food, Drug and Cosmetic Act, 21 U.S.C. §§301, et seq. (hereafter "the Food and Drug Act"), a licensed physician is permitted to use a federally-approved drug in an unapproved manner, provided such use is limited to his own patients.

> If an approved new drug is shipped in interstate commerce with the approved package insert, and neither the shipper

nor the recipient intends that it be used for an unapproved purpose, the requirements of section 505 of the Act are satisfied. Once the new drug is in a local pharmacy after interstate shipment, the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert, without informing or obtaining the approval of the Food and Drug Administration.

This interpretation of the Act is consistent with congressional intent as indicated in the legislative history of the 1938 Act and the drug amendments of 1962. Throughout the debate leading to enactment, there were repeated statements that Congress did not intend the Food and Drug Administration to interfere with medical practice and references to the understanding that the bill did not purport to regulate the practice of medicine as between the physician and the patient. Congress recognized a patient's right to seek civil damages in the courts if there should be evidence of malpractice, and declined to provide any legislative restrictions upon the medical profession.

Notice of Proposed Rule Making, submitted by FDA Commissioner Charles C. Edwards, 37 Fed. Reg. 16503 (August 15, 1972) (emphasis added).

A recent article written by an Assistant to the Director for Regulatory Affairs in the FDA Bureau of Drugs and a Professor of Law and Director of the FDA Unit at Temple Law School states the following:

> It should be apparent then that the medical practitioner has considerable freedom and authority for varied use of products.
>
> The physician can use the drugs exactly as labeled, or he may innovate prescriptively as to dosage, duration, concomitant drugs, precautionary recommendations and even new indications. Whether this is done directly or through the pharmacist, the federal law has been devoid of application inasmuch as the physician and pharmacist are

> engaged in the practice of their professional prerogatives. Therefore, parenteral mixtures as well as other mixtures prepared or prescribed by a physician for use on his own patients in the normal course of his practice are exempt from the new drug requirements and most other federal and state restrictions.

McEniry & Willig, The Federal Food, Drug, and Cosmetic Act and the Medical Practitioner, 29 Food Drug Cosmetic L.J. 548, 552 (November, 1974). Also see FTC v. Simeon Management Corporation, 1975 Trade Cases ¶60,223 (N.D.Cal. 1975).

Thus, assuming that "Liefcort" is a "new drug" under the Food and Drug Act, which could not be sold commercially without complying with the new drug procedures (see 21 U.S.C. §355), this does not mean that petitioner, a licensed physician,

cannot prescribe a combination of the federally-approved component drugs prednisone, testosterone and estradiol to her own patients within the scope of her medical practice.

The basis of petitioner's prayer for declaratory and injunctive relief is thus readily apparent. Even if petitioner prescribes, for her own patients, the combination of approved drugs which respondents refer to as "Liefcort," this is not in violation of the Food and Drug Act, nor is it activity over which the FDA has regulatory jurisdiction.

With specific regard to Section 704, the so-called "factory inspection"

statute* upon which respondents rely for authority to inspect petitioner's office, there is an express exemption as to

> practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propogate, compound, or process drugs solely for use in the course of their professional practice.

21 U.S.C. §374(a)(2). There are similar exemptions for licensed physicians throughout the drug regulatory provisions of the Food and Drug Act. See 21 U.S.C. §§353 (b)(2), 360 (g)(2).

Furthermore, the legislative

*See generally, Developments in the Law--The Federal Food, Drug, and Cosmetic Act, 67 Harv.L.Rev. 632, 686 (1954); The Drug Amendments of 1962, 38 N.Y.U. L.Rev. 1082, 1110 (1963); Graham, The Law Governing FDA Factory Inspection, 21 Food Drug Cosmetic L.J. 275 (1966); Aarons, Factory Inspection, 22 Food Drug Cosmetic L.J. 407 (1967).

history of the Food and Drug Act makes it clear that

> The word "drug" is not intended to apply to preparations dispensed by a doctor himself in the course of his professional practice.

79 Cong.Rec. 5019 (1935). Yet such preparations are precisely what respondents sought to inspect at petitioner's medical office.

And finally, since FDA lacks the underlying regulatory authority over petitioner's medical practice, warrantless administrative inspection would clearly be violative of the Fourth Amendment as construed in Camara v. Municipal Court, 387 U.S. 523 (1967); See v. City of Seattle, 387 U.S. 541 (1967); Colonnade Catering

Corp. v. United States, 397 U.S. 72 (1970); and United States v. Biswell, 406 U.S. 311 (1972).

CONCLUSION

For the foregoing reasons, a writ of certiorari should issue to review the judgment and opinion of the Court of Appeals for the Second Circuit.

Respectfully submitted,

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APPENDIX

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

No. 878—September Term, 1975.

(Argued April 22, 1976 Decided May 27, 1976.)

Docket No. 75-6109

ELIZABETH DALEY, M.D.

Plaintiff-Appellant,

—against—

F. DAVID MATHEWS, Secretary of Health, Education and Welfare, ALEXANDER M. SCHMIDT, M.D., Commissioner of Food and Drugs, CLIFFORD G. SHANE, Regional Director of the Food and Drug Administration, TERRY MUSSON, ALLEN R. HALPER, JOHN E. KLEMMER and THOMAS D. GARDINE, Employees of the Food and Drug Administration,

Defendants-Appellees.

Before:

MEDINA, FEINBERG and GURFEIN,

Circuit Judges.

Appeal from an order of the United States District Court for the Eastern District of New York, Edward R. Neaher, *Judge.*

Plaintiff Elizabeth Daley, M.D., appeals from an order which granted the motion of the defendants to dismiss the complaint on the ground that the controversy is not

ripe for adjudication. Opinion reported below, 400 F.Supp. 1288 (E.D.N.Y. 1975).

Affirmed.

HENRY B. ROTHBLATT, New York, N.Y. (Jon G. Rothblatt and Rothblatt, Rothblatt, Seijas & Peskin, New York, N.Y., on the brief), *for Plaintiff-Appellant.*

CYRIL HYMAN, Assistant United States Attorney, Brooklyn, New York (David G. Trager, United States Attorney, Eastern District of New York, Paul B. Bergman, Assistant United States Attorney, Brooklyn, New York, Richard A. Merrill, Chief Counsel, Rockville, Maryland, and Forrest T. Patterson, Associate Chief Counsel, Washington, D.C., of the United States Food and Drug Administration, on the brief), *for Defendants-Appellees.*

MEDINA, *Circuit Judge:*

Following two attempts by inspectors of the Food and Drug Administration ("FDA") to enter and inspect her medical offices, appellant Elizabeth Daley, M.D., commenced this action under 28 U.S.C. Section 1331 and Section 1337 seeking a declaratory judgment that the FDA lacks jurisdiction to inspect her offices pursuant to the provisions of the Food, Drug, and Cosmetic Act, 21 U.S.C. Section 301, *et seq.*, and seeking an injunction against any future inspection. The District Court, Judge Neaher, Eastern District of New York, granted defendants' motion for summary judgment and dismissed the complaint on

the ground that a controversy sufficiently ripe for adjudication does not presently exist between the parties. 400 F.Supp. 1288 (E.D.N.Y. 1975).

I

Dr. Daley is a physician who specializes in the treatment of arthritis, a disease from which she herself suffers. As part of the therapy which she administers to her patients, Dr. Daley uses three drugs, prednisone, testesterone, and estradiol, in combination. The FDA contends that one of the compounds of these drugs, Liefcort, is unapproved and dangerous, and that appellant uses and dispenses this illegal compound. Dr. Daley counters that the three drugs which form the Liefcort compound are federally approved, and that in any case, the FDA lacks authority to inspect her office under Section 704(a) of the Food, Drug and Cosmetic Act, 21 U.S.C. Section 374(a)[1] as that Section exempts physicians licensed by law to prescribe or administer drugs.

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1 §374. Inspection—Right of agents to enter; scope of inspection; notice; promptness; exclusions

(a) For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any * * * establishment in which * * * drugs * * * are manufactured, processed, packed, or held, for introduction into interstate commerce * * * and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such * * * establishment * * * and all pertinent equipment, finished and unfinished materials; containers, and labeling therein. In the case of any * * * establishment * * * in which prescription drugs are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held

On February 10, 1975, an FDA inspector attempted to gain entry into appellant's offices in order to carry out an inspection. After he presented a notice of inspection, a nurse then on duty stated that appellant was not in and refused to permit the inspection. She advised the investigator that any inquiries regarding Dr. Daley should be directed to the latter's attorneys. Several weeks later, appellant's attorney contacted Officer Musson of the FDA, informing him that Dr. Daley would not permit an inspection of her offices but would provide any information the FDA requested concerning medications used in her practice.

On February 27, 1975, another inspection was attempted by two other investigators on a day that Dr. Daley maintained office hours. Finding the office door locked, they rang the bell and were met by the nurse who once again refused to permit entry. After being given another notice of inspection, the nurse advised the investigators that Dr. Daley was not in the office that day and repeated that they should contact the Doctor's attorneys. No further inspections were attempted.

II

Even though the FDA still maintains that Dr. Daley is continuing her illegal use of Liefcort, there is no showing of any intention or threat again to inspect the Doctor's office in search of the drug. Notwithstanding this uncertainty, Dr. Daley nonetheless contends that there now exists an actual controversy between the parties and that she has

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in any such place, or otherwise bearing on violation of this chapter. * * * The provisions of the second sentence of this subsection shall not apply to—

* * * * *

(2) practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound, or process drugs solely for use in the course of their professional practice * * *.

already suffered and continues to suffer substantial injury to such an extent that immediate relief is necessary. She claims that continued investigation by appellees will destroy her professional reputation and drive away patients, and that the FDA's actions represent an unwarranted and unlawful intrusion on her right to practice medicine in accordance with her own professional judgment and skill.

Despite such anxiety which Dr. Daley may have suffered as a result of the FDA's indecisive behavior, we are constrained to agree with the court below that there does not yet exist a ripe case or controversy on which to found declaratory or injunctive relief. All that the FDA has done was to appear on two occasions and request permission to inspect the physician's offices. It is not even clear that the Doctor herself refused to allow the inspections. Following the two visits by FDA investigators, Dr. Daley proposed that an inspection be arranged in the presence of her attorney, but this suggestion was rejected by the FDA for the understandable reason that to follow such a course would eliminate the element of surprise and perhaps frustrate the purpose of the inspection. The FDA has declined to take any affirmative action which could ripen the controversy for judicial review. It is thus impossible to predict whether the agency will attempt another inspection, whether it will seek to obtain an injunction under 21 U.S.C. Section 332 or an inspection warrant upon a showing of probable cause compelling Dr. Daley to permit inspection, whether it will institute criminal proceedings against the Doctor under 21 U.S.C. Sections 331(f) and 333(a), whether it will eventually accede to Dr. Daley's offer of an inspection with counsel present or whether it will simply do nothing. We have repeatedly stated that, particularly where agency action is involved, courts will not and should not intervene unless the need for equitable relief is more

than remote or speculative. *See, e.g., American Dietaids Co., Inc.* v. *Celebrezze,* 317 F.2d 658, 660 (2d Cir.), *cert. denied,* 375 U.S. 896 (1963). That requisite certainty is absent here.

In a trilogy of decisions [*Abbott Laboratories* v. *Gardner,* 387 U.S. 136 (1967); *Toilet Goods Assn., Inc.* v. *Gardner,* 387 U.S. 158 (1967); *Gardner* v. *Toilet Goods Assn., Inc.,* 387 U.S. 167 (1967)] the Supreme Court made clear that in assessing the fitness for review of challenges to pre-enforcement agency action, a major consideration is the hardship to the plaintiff which will flow from withholding judicial review. Dr. Daley's situation is unlike that of the plaintiffs in *Gardner* v. *Toilet Goods Assn., Inc., supra,* and *Abbott Laboratories* v. *Gardner, supra,* where immediate adverse consequences would predictably have resulted from judicial abstention, and where the FDA's actions required an immediate and significant change in plaintiffs' conduct of their affairs. At bottom all that appellant here suffers is the tentative possibility of a future inspection; it is not even clear that the FDA will attempt to require her to cease dispensing the drugs involved. Seemingly her situation is more closely analogous to that in *Toilet Goods Assn., Inc.* v. *Gardner, supra,* where the Court found that "consideration of the underlying legal issues would necessarily be facilitated if they were raised in the context of a specific attempt to enforce the regulations." 387 U.S. at 171 [footnote omitted].

Judge Neaher expressed no view on the merits of Dr. Daley's contentions regarding the legality of inspection under Section 704(a), nor do we. The judgment dismissing the complaint is affirmed.

Affirmed.

Elizabeth DALEY, M.D., Plaintiff,
v.
Caspar W. WEINBERGER, Secretary of Health, Education and Welfare, et al., Defendants.
No. 75 C 306.

United States District Court,
E. D. New York.
Oct. 3, 1975.

A physician sought declaratory and injunctive relief to prevent the Food and Drug Administration from any further attempts to conduct an inspection of her office. On motion by the FDA to dismiss or for summary judgment, the District Court, Neaher, J., held that where the only action taken by FDA was to post two notices of inspection to be served on the physician and to question the physician's nurse, and the notices merely recited various statutory provisions authorizing FDA inspections without specifying purpose of inspection or what the FDA expected to find, there was no final agency action whose legality the court could pass upon, and there was no justiciable controversy, though the issue raised, i. e., FDA's statutory authority to inspect a physician's office, appeared to be a purely legal one. Absent compelling circumstances, there was no basis for the court to issue judgment declaring in advance of criminal prosecution that acts already committed or even to be committed in the future were or were not unlawful.

Motion for summary judgment dismissing complaint granted.

1. Declaratory Judgment ⇐62

Where preenforcement attack is made on validity of administrative action, test of justiciable controversy involves evaluation of both fitness of issues for judicial decision and hardship to parties of withholding court consideration, and first part of test, i. e., fitness of issues for resolution, itself consists of two parts: whether issues raised are purely legal in nature and whether challenged agency action was final.

2. Drugs and Narcotics ⇐10

Federal Drug Administration is not required under inspection statute to set forth in its notice the reason underlying inspection or what it expects to find; FDA is simply and unequivocally authorized to enter and inspect certain specified premises at reasonable times. Federal Food, Drug, and Cosmetic Act, §§ 704, 704(a), 21 U.S.C.A. §§ 374, 374(a); U.S.C.A.Const. Amend. 4.

3. Declaratory Judgment ⇐203

Where only action taken by Food and Drug Administration was to post two notices of inspection to be served on physician and to question physician's nurse, and notices merely recited various statutory provisions authorizing FDA inspections without specifying purpose of inspection or what FDA expected to find, there was no final agency action whose legality the court could pass upon, and there was no justiciable controversy, though issue raised, i. e., FDA's statutory authority to inspect a physician's office, appeared to be a purely legal one. Federal Food, Drug, and Cosmetic Act, §§ 301(f), 302, 303(a), 704, 704(a), 21 U.S.C.A. §§ 331(f), 332, 333(a), 374, 374(a); U.S.C.A.Const. Amend. 4.

4. Declaratory Judgment ⇐84

Absent compelling circumstances, there was no basis for court to issue judgment declaring in advance of criminal prosecution that acts already committed or even to be committed in the future were or were not unlawful. 28 U.S.C.A. §§ 1331, 1337; Fed.Rules Civ. Proc. rules 12(b)(6), 56, 28 U.S.C.A.

Rothblatt, Rothblatt, Seijas & Peskin, by Henry B. Rothblatt, Jon G. Rothblatt, New York City, for plaintiff.

David G. Trager, U. S. Atty. E.D.N.Y., by Cyril Hyman, Asst. U. S. Atty., Brooklyn, N.Y., for defendants.

MEMORANDUM AND ORDER

NEAHER, District Judge.

Plaintiff Elizabeth Daley, a licensed physician practicing in New York City, brought this action under 28 U.S.C. §§ 1331 and 1337 seeking declaratory and injunctive relief aimed at preventing defendants (hereinafter "FDA") from any further attempts to conduct an inspection of her office. The case is now before the court on FDA's motion to dismiss the complaint or in the alternative for summary judgment. Rules 12(b)(6) and 56, F.R.Civ.P.

In the course of plaintiff's practice it appears that she prescribes various drugs, including prednisone, testosterone, estradiol and combinations thereof, for patients suffering from rheumatic diseases, principally rheumatoid arthritis. She alleges that on or about February 10, 1975, defendant Allen R. Halper, an FDA investigator, visited her office

in New York City, interrogated a registered nurse in her employ and served a Notice of Inspection pursuant to Section 704(a) of the Food, Drug and Cosmetic Act, 21 U.S.C. § 374(a) ("the Act").[1] On or about February 27, 1975, two other FDA investigators, defendants John E. Klemmer and Thomas D. Gardine, appeared at plaintiff's office, interrogated

1. "§ 374. Inspection—Right of agents to enter; scope of inspection; notice; promptness; exclusions

"(a) For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any . . . establishment in which . . . drugs . . . are manufactured, processed, packed, or held, for introduction into interstate commerce . . . and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such . . . establishment . . . and all pertinent equipment, finished and unfinished materials; containers, and labeling therein. In the case of any . . . establishment . . . in which prescription drugs are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter. . . . The provisions of the second sentence of this subsection shall not apply to—

• • • • •

"(2) practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound, or process drugs solely for use in the course of their professional practice . . ."

the registered nurse and served a second Notice of Inspection.

Plaintiff believes that she is being investigated concerning a drug called Liefcort. Although she claims that FDA lacks jurisdiction under the Act [2] to investigate or inspect either her practice or the treatment she prescribes for her patients, she asserts her willingness to discuss with FDA officials, through her attorney, details of medications which she prepares, prescribes and administers to her patients.

FDA acknowledges that its desire to inspect plaintiff's premises stems from a belief that in the course of plaintiff's practice she may be distributing Liefcort, a drug not approved by FDA. Liefcort, which is apparently used outside this country in the treatment of arthritis, is believed to consist of prednisone, testosterone and estradiol, in proportions known only to its discoverer, the late Dr. Robert Liefmann. FDA believes that some of it may have been shipped into the country and found its way into plaintiff's offices.

Essentially four grounds are relied on in support of FDA's motion to dismiss or for summary judgment: (1) there is no justiciable controversy before the court; (2) FDA, an agency of the United States, has not consented to the suit and therefore it is barred by the doctrine of sovereign immunity; (3) there is an adequate remedy at law; and (4)

2. Plaintiff also claims that FDA's construction of § 374 violates the Fourth Amendment under the reasoning of *Colonnade Catering Corporation v. United States*, 397 U.S. 72, 90 S.Ct. 774, 25 L.Ed.2d 60 (1970), and *United States v. Biswell*, 406 U.S. 311, 92 S.Ct. 1593, 32 L.Ed.2d 87 (1972).

FDA does have the statutory authority to investigate plaintiff's offices.

[1] The absence of a justiciable controversy is premised on a lack of ripeness, a question necessarily involving a discretionary determination as to whether a particular controversy is appropriate for judicial resolution. In situations, such as this, where a pre-enforcement attack is made on the validity of administrative action, the Court, in the drug trilogy cases *Abbott Laboratories v. Gardner*, 387 U.S. 136, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967); *Toilet Goods Ass'n v. Gardner*, 387 U.S. 158, 87 S.Ct. 1520, 18 L.Ed.2d 697 (1967); *Gardner v. Toilet Goods Ass'n*, 387 U.S. 167, 87 S.Ct. 1526, 18 L.Ed.2d 704 (1967), has established guidelines for ascertaining the appropriateness of judicial intervention.

The test to be applied is twofold in nature and involves an evaluation of "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott, supra*, 387 U.S. at 149, 87 S.Ct. at 1515. The first part of the test, *i. e.*, the fitness of the issues for resolution, itself consists of two parts—whether the issues raised were purely legal in nature and whether the challenged agency action was final. *Id.*

In *Abbott, supra*, the plaintiffs had challenged the authority of the Secretary of Health, Education and Welfare to promulgate certain regulations, which had already been the subject of hearings and had been published in final form with immediate compliance expected. Applying the two-part test, the Court noted that the tendered issues were purely legal and the agency action was in every respect final, not tentative, and not the action of a subordinate official.

Abbott Laboratories, supra, 387 U.S. at 151, 87 S.Ct. 1507. Additionally, the challenged regulations would have "a direct effect on the day-to-day business of all prescription drug companies . . ." (387 U.S. at 152, 87 S.Ct. at 1517), and therefore withholding judicial consideration would necessitate considerable hardship. Under those circumstances, the Court departed from the otherwise settled rule that courts are to avoid "entangling themselves in abstract disagreements over administrative policies" and that administrative agencies are entitled to be free "from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Abbott Laboratories, supra*, 387 U.S. at 148–49, 87 S.Ct. at 1515.

[2, 3] In this case, the only action taken by FDA has been to cause two notices of inspection to be served and to question plaintiff's nurse. The notices merely recite various statutory provisions authorizing FDA inspections without specifying the purpose of the inspection or what FDA expects to find on the premises it seeks to enter.[3]

Applying the *Abbott Laboratories* test to these facts, the court is of opinion that discretion should not be exercised in favor of retaining jurisdiction. While the issue raised appears to be a purely legal one, *i. e.*, the FDA's statutory authority to inspect a physician's office, there is here no final agency action

3. Nor is FDA required under § 374 to set forth in its notice the reason underlying the inspection or what it expects to find; the section simply and unequivocally authorizes FDA to enter and inspect certain specified premises at reasonable times. See fn. 1.

whose legality the court may pass upon. Although FDA agents made two visits to plaintiff's office, no inspection was in fact conducted. The court is reluctant to anticipate what future action, if any, FDA may decide to take.

In *American Dietaids Co., Inc. v. Celebrezze*, 317 F.2d 658 (2 Cir. 1963), the court affirmed the dismissal of an action brought to enjoin FDA inspectors from using concealed tape recorders during future inspections of a plaintiff's premises, saying:

> "There is no ground in such a single past incident for declaratory relief against possible future inspections. There is no actual controversy now existing on which to found declaratory relief. . . . 'Especially where governmental action is involved, courts should not intervene unless the need for equitable relief is clear, not remote or speculative.' [Quoting from *Eccles v. People's Bank of Lakewood Village, Cal.*, 333 U.S. 426, 431, 68 S.Ct. 641, 644, 92 L.Ed. 784.]" 317 F.2d at 660.

That language is apposite here.

This case is also distinguishable from *Abbott* and *Gardner* on the question of the hardship of withholding judicial consideration at this time. In those cases the challenged regulations required the plaintiffs to take positive action which would have had "a direct effect on the[ir] day-to-day business . . . ." Here, no action on plaintiff's part is required—the ball, so to speak, is in FDA's court.

If FDA decides to pursue the matter further, there are two courses of action available. First, if FDA desires to enforce its claimed right of inspection un-

der § 374, it will have to seek the court's aid under § 332, which grants the district courts jurisdiction to enjoin violations of § 331. Subdivision (f) of § 331 prohibits "[t]he refusal to permit entry or inspection as authorized by section 374 . . ." If relief were granted under § 332 the occupant (plaintiff here) would be enjoined from refusing entry to FDA inspectors. *Cf. Brennan v. Buckeye Industries, Inc.*, 374 F.Supp. 1350 (S.D.Ga.1974). In such a proceeding plaintiff would have the opportunity to explain to the court her reasons for denying entry to the FDA inspectors and the legal issue raised could then be properly decided. See, *e. g., FTC v. Simeon Management Corporation*, 391 F. Supp. 697 (N.D.Cal.1975).

Second, FDA could institute criminal proceedings against plaintiff under 21 U.S.C. § 333(a),[4] in which event she could raise as a defense FDA's lack of authority to inspect her office. See, *e. g., United States v. Thriftimart, Inc.*, 429 F.2d 1006 (9 Cir.), *cert. denied*, 400 U.S. 926, 91 S.Ct. 188, 27 L.Ed.2d 185 (1970).

Plaintiff urges that she should not be required to test the legality of FDA's right to inspect her office in a criminal proceeding, on pain of conviction should she lose. Her fear of prosecution, however, is not a sufficient predicate for this court to retain jurisdiction. Here, there is no indication that the government intends to prosecute plaintiff either for her past two refusals to permit entry or for any future refusals—unlike

4. Section 333(a) provides:
"Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both."

the situation in *Doe v. Bolton*, 410 U.S. 179, 93 S.Ct. 739, 35 L.Ed.2d 201 (1973), where physicians challenged the constitutionality of a Georgia abortion statute under whose predecessors doctors were actually prosecuted. *Cf. Laird v. Tatum*, 408 U.S. 1, 13, 92 S.Ct. 2318, 2325, 33 L.Ed.2d 154 (1972),[5] and *Socialist Workers Party v. Attorney General of the United States*, 510 F.2d 253 (2 Cir. 1974).

[4] Moreover, absent compelling circumstances, such as presented in the *Doe* case, there is no basis for a court to issue a judgment declaring in advance of a criminal prosecution that acts already committed, or even to be committed in the future, are or are not unlawful. *Cf. Ewing v. Mytinger & Casselberry*, 339 U.S. 594, 599, 70 S.Ct. 870, 94 L.Ed. 1088 (1950).

5. In refusing to permit a suit under the First Amendment seeking declaratory and injunctive relief against surveillance being conducted by the Army, the Court noted:
"At the same time, however, these decisions have in no way eroded the 'established principle that to entitle a private individual to invoke the judicial power to determine the validity of executive or legislative action he must show that he has sustained, or is immediately in danger of sustaining, a direct injury as the result of that action . . . .' *Ex parte Levitt*, 302 U.S. 633, 634, 58 S.Ct. 1, 82 L.Ed. 493 (1937)."
The Court went on to conclude that to allow the action to proceed
"would have the federal courts as virtually continuing monitors of the wisdom and soundness of Executive action: such a role is appropriate for the Congress acting through its committees and the 'power of the purse'; it is not the role of the judiciary, absent actual present or immediately threatened injury resulting from unlawful governmental action." 408 U.S. at 15, 92 S.Ct. at 2326.

Finally, in construing statutes providing criminal penalties for individuals who refuse to honor administrative summonses, the courts have held in parallel situations that good faith noncompliance is not subject to prosecution. See *Reisman v. Caplin*, 375 U.S. 440, 446–49, 84 S.Ct. 508, 11 L.Ed.2d 459 (1964) (good faith refusal to honor an internal revenue service summons would be a defense to a prosecution under 26 U.S.C. § 7210).[6] Similarly, in *Anheuser-Busch, Inc. v. Federal Trade Commission*, 359 F.2d 487 (8 Cir. 1966) (Blackmun, J.), the court held that § 10 of the Federal Trade Commission Act, 15 U.S.C. § 50, which makes it an offense to refuse "to answer any lawful inquiry . . . if in [one's] power to do so, in obedience to the subpoena or lawful requirement of the commission . . . ", does not authorize criminal prosecution "where the challenge to the subpoena is in good faith." 359 F.2d at 490. See also *Federal Power Commission v. Metropolitan Edison Co.*, 304 U.S. 375, 386–87, 58 S. Ct. 963, 82 L.Ed. 1408 (1938).

The court concludes that a controversy sufficiently ripe for adjudication does not presently exist between the parties. Defendants' motion for summary judgment dismissing the complaint is there-

6. Section 7210 provides:
"Any person who, being duly summoned to appear to testify, or to appear and produce books, accounts, records, memoranda, or other papers . . . neglects to appear or to produce such books, accounts, records, memoranda, or other papers, shall, upon conviction thereof, be fined not more than $1,000, or imprisoned not more than 1 year, or both, together with costs of prosecution."

fore granted.[7]

So ordered.

7. Accordingly, it is not necessary for the court either to wade through the murky waters of sovereign immunity or to decide whether the *Reisman*, *supra*, and *Anheuser-Busch*, *supra*, cases mandate a dismissal of the action for want of equity.

United States Court of Appeals

SECOND CIRCUIT

At a Stated Term of the United States Court of Appeals, in and for the Second Circuit, held at the United States Court House, in the City of New York, on the 20th day of July , one thousand nine hundred and seventy-six

Present: HON. HAROLD R. MEDINA,

HON. WILFRED FEINBERG,

HON. MURRAY I. GURFEIN,

Circuit Judges.

Elizabeth Daley, M.D., Plaintiff-Appellant, v. F. David Mathews, Secretary of Health, Education and Welfare, Alexander M. Schmidt, M.D., Commissioner of the Food and Drug Administration, Terry Musson, Allen R. Halper, John E. Klemmer, and Thomas D. Gardine, Employees of the Food and Drug Administration, Defendants-Appellees.	75-6109

A petition for a rehearing having been filed herein by counsel for the appellant

Upon consideration thereof, it is

Ordered that said petition be and hereby is denied.

A. Daniel Fusaro

A. DANIEL FUSARO, Clerk

AMENDED COMPLAINT

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

ELIZABETH DALEY, M.D. and HENRY ROSENBERG, M.D.

Plaintiffs,

-against-

CASPAR W. WEINBERGER, Secretary of Health, Education and Welfare, ALEXANDER M. SCHMIDT, M.D., Commissioner of the Food and Drug Administration, CLIFFORD G. SHANE, Regional Director of the Food and Drug Administration, TERRY MUSSON, ALLEN R. HALPER, JOHN E. KLEMMER and THOMAS D. GARDINE, Employees of the Food and Drug Administration,

Defendants.

AMENDED COMPLAINT

75-C-306

Plaintiffs, by their attorneys, ROTHBLATT, ROTHBLATT, SEIJAS and PESKIN, allege as follows:

Jurisdiction

1. This action arises under the Fourth, Fifth and Sixth Amendments of the United States Constitution and the Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. §§ 301, et seq., as hereinafter more fully appears. The matter in controversy exceeds, exclusive of interest and costs, the value of ten thousand dollars.

2. Jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337.

3. This is an action for a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure, and a declaratory judgment pursuant to 28 U.S.C. § 2201.

AMENDED COMPLAINT

Parties

4. Plaintiff ELIZABETH DALEY, M.D. is a physician duly licensed to practice medicine in the State of New York.

5. Plaintiff HENRY ROSENBERG, M.D. is a physician duly licensed to practice medicine in the State of New York.

6. Defendant CASPAR W. WEINBERGER is Secretary of the United States Department of Health, Education and Welfare.

7. Defendant ALEXANDER M. SCHMIDT, M.D., is Commissioner of the Food and Drug Administration of the United States Department of Health, Education and Welfare.

8. Defendant CLIFFORD G. SHANE is the Regional Director of the Food and Drug Administration.

9. Defendant TERRY MUSSON is an employee of the Food and Drug Administration.

10. Defendant ALLEN R. HALPER is an Investigator employed by the Food and Drug Administration.

11. Defendant JOHN E. KLEMMER is an Investigator employed by the Food and Drug Administration.

12. Defendant THOMAS D. GARDINE is an Investigator employed by the Food and Drug Administration.

Plaintiffs' Medical Practice

13. Plaintiffs DALEY AND ROSENBERG are engaged in the practice of medicine in the State of New York and maintain offices for this purpose at 320 West End Avenue, New York City, New York.

AMENDED COMPLAINT

14. In the course of their medical practice, plaintiffs DALEY and ROSENBERG prescribe various medications, vitamins and diets for their patients in the treatment of rheumatoid arthritis and other rheumatic diseases. These medications include the drugs "prednisone," "testosterone," "estradiol," and combinations thereof.

15. Said drugs are all fully approved under applicable federal law for use in the professional practice of medicine.

16. The conduct of plaintiffs DALEY and ROSENBERG in preparing, prescribing and administering said drugs and combinations thereof to their patients is their lawful right and professional prerogative as duly licensed medical practitioners.

17. It is the professional judgment and opinion of plaintiffs DALEY and ROSENBERG that the administration of said drugs to their patients suffering from rheumatic diseases is indispensable to effective medical treatment, and that without the use of said drugs their patients' conditions would substantially deteriorate, resulting in increased pain, suffering and crippling to hundreds of individuals.

Defendants' Conduct

18. On or about February 10, 1975, defendant HALPER appeared at plaintiffs' offices at 320 West End Avenue, New York City, New York.

19. During said February 10, 1975 appearance at plaintiffs' offices, defendant HALPER interrogated Donna Pinorsky, R.N.

about various aspects of plaintiff's medical practice and treatment of patients.

20. During said February 10, 1975 appearance at plaintiffs' offices, defendant HALPER did also serve upon Donna Pinorsky, R.N., a Notice of Inspection pursuant to Section 704 (a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 374 (a), a copy of which is annexed hereto and marked Exhibit "A."

21. On or about February 27, 1975, defendants KLEMMER and GARDINE appeared at plaintiffs' offices at 320 West End Avenue, New York City, New York.

22. During said February 27, 1975 appearance at plaintiffs' offices, defendants KLEMMER and GARDINE interrogated Donna Pinorsky, R.N.

23. During said February 27, 1975 appearance at plaintiffs' offices, defendants KLEMMER and GARDINE did also serve upon Donna Pinorsky, R.N., a Notice of Inspection pursuant to Section 704(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 374(a), a copy of which is annexed hereto and marked Exhibit "B."

24. Subsequent to February 10, 1975, and prior to February 27, 1975, plaintiffs' attorney, Henry B. Rothblatt, had telephone conversations with defendants KLEMMER and MUSSON concerning the purpose of the Notice of Inspection and the future intentions of the Food and Drug Administration with regard to plaintiffs DALEY and ROSENBERG.

25. Upon information and belief, the Food and Drug Administration is conducting an investigation of plaintiffs' medical practice, and intends to continue said investigation, to include interrogation of plaintiffs as well entry and inspection of their offices at 320 West End Avenue, New York City, New York.

26. Upon information and belief, the claimed justification for the aforementioned investigation are alleged violations of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., concerning a "new drug" known as "Leifcort."

27. Plaintiffs have offered to fully disclose and openly discuss with appropriate Food and Drug Administration officials, through their attorney, all relevant details concerning the medications which they prepare, prescribe and administer to their patients. A copy of correspondence sent to the Food and Drug Administration to this effect is annexed hereto and marked Exhibit "C."

28. To date defendants have not availed themselves of the opportunity to resolve this matter through discussion with plaintiffs' attorney. As a result, the issue remains unresolved, and plaintiffs must continue to function under a constant threat of impending action against them by the Federal Government.

Defendants' Lack of Jurisdiction

29. As previously alleged herein, plaintiffs DALEY and ROSENBERG have the absolute right, as duly licensed physicians,

to prepare, prescribe and administer approved drugs and combinations thereof to their own patients in the course of their medical practice.

30. The Federal Government, and specifically the Food and Drug Administration under the provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., lacks jurisdiction and authority to investigate, inspect, or in any manner interfere with plaintiffs' medical practice and treatment of patients.

Injury

31. The conduct of the Food and Drug Administration, its officers and employees, in investigating, inspecting threatening to do the same, or otherwise interferring with plaintiffs' right to practice medicine, is violative of the Fourth, Fifth and Sixth Amendments of the United States Constitution, the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., as well as the physician-patient privilege.

32. Said conduct of the Food and Drug Administration, its officers and employees, has caused and will continue to cause further irreparable injury to plaintiffs and their patients in that:

(a) Plaintiffs are being deprived of their right to be free from unreasonable search and seizure;

(b) Plaintiffs are being deprived the right of effective assistance of counsel by defendants' refusal to discuss the matters in issue with plaintiffs' attorney;

(c) Defendants seek to prevent plaintiffs from lawfully practicing medicine in accordance with their own professional judgment and skill, in violation of the right to due process of law;

(d) Defendants seek to prevent plaintiffs from rendering effective medical treatment to their patients, which will result in increased pain, suffering and crippling of hundreds of individuals suffering from rheumatoid arthritis and other rheumatic diseases;

(e) Continued investigation by defendants will destroy plaintiffs' professional reputation, cause them to lose patients, and otherwise result in substantial permanent injury;

(f) Plaintiffs are being unlawfully subjected to possible criminal prosecution and resulting fine, imprisonment and loss of their licenses to practice medicine for refusal to permit an unauthorized inspection of their offices and/or other violations of the Food, Drug and Cosmetic Act, 21 U.S.C. § 331.

33. Said conduct of the Food and Drug Administration, its officers and employees, will continue unless permanently enjoined by this Court.

34. There is an actual controversy between the parties herein concerning defendants' authority and jurisdiction to in-

vestigate, inspect and otherwise interfere with plaintiffs' medical practice.

35. Plaintiffs have no adequate remedy at law.

WHEREFORE, plaintiffs respectfully request a judgment:

(a) Declaring that the Federal Government, and specifically the Food and Drug Administration of the Department of Health, Education and Welfare, lacks authority and jurisdiction to investigate, inspect or otherwise enforce the provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., against plaintiffs for their conduct in preparing, prescribing and administering approved drugs or combinations thereof to their own patients in the course of their medical practice.

(b) Enjoining and restraining defendants, their agents, employees, successors, and all other persons acting in their behalf, during the pendency of this litigation and thereafter permanently, from investigating, inspecting or otherwise enforcing the provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., against plaintiffs for their conduct in preparing, prescribing and administering approved drugs or combinations thereof to their own patients in the course of their medical practice;

(c) Awarding plaintiffs costs and such other and further relief as to this court seems just and proper.

DATED: New York, New York
March 3, 1975

Respectfully submitted,

ROTHBLATT, ROTHBLATT,
SEIJAS & PESKIN
Attorneys for Plaintiffs
323 West End Avenue
New York, New York 10023
(212) 787-7001

AMENDED COMPLAINT

VERIFICATION

STATE OF NEW YORK)
)
COUNTY OF NEW YORK) ss.:

HENRY ROSENBERG, M.D., being duly sworn, deposes and says that he is a plaintiff in the within action; that he has read the foregoing amended complaint and knows the contents thereof; that the same is true to his own knowledge except as to matters therein stated to be alleged on information and belief; and that as to those matters he believes it to be true.

Henry Rosenberg, M.D.
HENRY ROSENBERG, M.D.

Sworn to before me this
3 day of March 1975

[illegible]
Notary Public, State of New York
Qualified in New York County
Commission Expires March 30, 1976

[illegible] 525-1543 465-5123

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS
850 3rd Avenue
Brooklyn, N.Y. 11232

TO
2. NAME AND TITLE OF INDIVIDUAL
Irene Pacella R.N.
3. DATE
2/10/75
4. FIRM NAME
Dr. Donald Rubin & Rutkow Laboratory
5. NUMBER AND STREET
320 West Edna
5. HOUR
11 10 a.m. p.m.
7. CITY AND STATE
New York, N.Y.
8. ZIP CODE
10023

Notice of inspection is hereby given pursuant to Section 704(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 USC 262-264].[2]

9. SIGNATURE (Food and Drug Administration Employee(s))
[illegible]
10. TITLE (Food and Drug Administration Employee(s))
Investigator

[1]Applicable portions of Section 704 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704. (a) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and (E) research data (other than data, relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (j) or section 507 (c) or (g) of this Act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505 (j) of this Act). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

[2]Applicable sections of Parts F and G of Title III Public Health Service Act [42 USC 262 – 264] are quoted below:

Part F – Licensing – Biological Products and Clinical Laboratories and ******

Sec. 351(c) "Any officer, agent, or employee of the Department of Health, Education, and Welfare, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F – ***** Control of Radiation.

Sec. 360 A(a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(n) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

Part G – Quarantine and Inspection.

Sec. 361(a) "The Surgeon General, with the approval of the Secretary is authorized to make and enforce such regulations as in his judgement are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgement may be necessary."

FORM FD 482 (10/73) PREVIOUS EDITION IS OBSOLETE NOTICE OF INSPECTION

BEST COPY AVAILABLE

AMENDED COMPLAINT

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS
850 Third Ave.
Brooklyn, N.Y. 11232

TO
2. NAME AND TITLE OF INDIVIDUAL
Grace Cooke R.N.
3. DATE
2-27-75
4. FIRM NAME
Dr Elizabeth Daley & Dr Margo Rowley
5. NUMBER AND STREET
320 West End Avenue
HOUR
10:30 a.m.
7. CITY AND STATE
New York, N.Y.
8. ZIP CODE
10023

Notice of inspection is hereby given pursuant to Section 704(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 USC 262-264].[2]

9. SIGNATURE (Food and Drug Administration Employee(s))
Thomas F. Cooke
10. TITLE (Food and Drug Administration Employee(s))
INVESTIGATORS

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[2] Applicable sections of Parts F and G of Title III Public Health Service Act [42 USC 262 – 264] are quoted below:

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Part F – ***** Control of Radiation.

Sec. 360 A(a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(b) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

Part G – Quarantine and Inspection.

Sec. 361(a) "The Surgeon General, with the approval of the Secretary is authorized to make and enforce such regulations as in his judgement are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgement may be necessary."

FORM FD 482 (10/73) PREVIOUS EDITION IS OBSOLETE NOTICE OF INSPECTION

AMENDED COMPLAINT

MGMNYIT MSB
2-046999E055002 02/24/75 western union Mailgram
ICS IPMMTZZ CSP
1 2127877001 MGM TDMT NEW YORK NY 02-24 0946P EST
ZIP 10023

HENRY B ROTHBLATT
232 WEST END AVE
NEW YORK NY 10023

THIS MAILGRAM IS A CONFIRMATION COPY OF THE FOLLOWING MESSAGE:

2127877001 MGM TDMT NEW YORK NY 100 02-24 0946P EST
ZIP
INSPECTOR JOHN KLEMMER
FOOD AND DRUG ADMINISTRATION
850 3 AVE
BROOKLYN NY 11232
WOULD YOU PLEASE INFORM ME THE BASES OF YOUR JURISDICTION TO INTERROGATE A MEDICAL DOCTOR SUCH AS DOCTOR DALEY CONCERNING HER MEDICATION AND PRESCRIPTION AND TREATMENT OF HER PATIENTS AS A DULY LICENSE PHYSICIAN. AS I TOLD YOU IN OUR TELEPHONE CONVERSATION I WILL BE PLEASED TO DISCUSS ALL ASPECT OF THESE MEDICATIONS WITH YOUR SUPERIORS AND ATTORNEYS
HENRY B ROTHBLATT ATTORNEY FOR DR ELIZABETH DALEY
232 WEST END AVE
NEW YORK NY 10023

21:46 EST

MGMNYIT MSB

Supreme Court, U. S.
FILED
FEB 24 1977
MICHAEL RODAK, JR., CLERK

No. 76-686

In the Supreme Court of the United States

OCTOBER TERM, 1976

ELIZABETH DALEY, M.D., PETITIONER

v.

JOSEPH A. CALIFANO, JR., SECRETARY OF HEALTH, EDUCATION AND WELFARE, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

DANIEL M. FRIEDMAN,
Acting Solicitor General,

DONALD I. BAKER,
Assistant Attorney General,

ROBERT B. NICHOLSON,
ANDREA LIMMER,
Attorneys,
Department of Justice,
Washington, D.C. 20530.

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Section 301, 21 U.S.C. 331 ..... 2, 4

Section 301(f), 21 U.S.C. 331(f) 4, 9

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Section 704(a), 21 U.S.C. 374(a), as amended by Pub. L. 94-295, Sec. 6, 90 Stat. 581 ..... 2, 4, 6, 8, 13, 14

In the Supreme Court of the United States

OCTOBER TERM, 1976

No. 76-686

ELIZABETH DALEY, M.D., PETITIONER

v.

JOSEPH A. CALIFANO, JR., SECRETARY OF HEALTH, EDUCATION AND WELFARE, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-6a) is reported at 536 F. 2d 519. The memorandum and order of the district court (Pet. App. 7a-18a) are reported at 400 F. Supp. 1288.

JURISDICTION

The judgment of the court of appeals was entered on May 27, 1976.[1] A timely petition for rehearing was denied on July 20, 1976 (Pet. App. 21a). A petition for

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[1]The appendix to the petition does not include a copy of the judgment, as required by Rule 23.1(j) of the Rules of this Court.

a writ of certiorari was filed on October 18, 1976.[2] The jurisdiction of this Court is invoked purusant to 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether petitioner's complaint for declaratory and injunctive relief, based on a claim that Section 704(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 374(a), does not authorize the Food and Drug Administration to inspect the offices at which she conducts her medical practice, was sufficiently ripe for adjudication.

STATUTES INVOLVED

The relevant portions of 21 U.S.C. 331 and 333 (Sections 301 and 303 of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1042, 1043, as amended), are printed at Pet. 6. The relevant portion of 21 U.S.C. 374(a) (Section 704(a) of the Act, 52 Stat. 1057, as amended by Pub. L. 94-295, Sec. 6, 90 Stat. 581) provides:

> For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, * * * and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory,

[2] The Court received the petition on October 18, 1976, but it was returned to counsel for reprinting. The petition was again received on November 17, 1976, and docketed as of the date of the original submission.

> warehouse, establishment, * * * and all pertinent equipment, finished and unfinished materials; containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs or restricted devices are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs or restricted devices which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter. * * * The provisions of the second sentence of this subsection shall not apply to—
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> * * * * *
>
> (2) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices, solely for use in the course of their professional practice;
>
> * * * * *

21 U.S.C. 332(a) (Section 302(a) of the Act, 52 Stat. 1043, as amended) provides in pertinent part:

> The district courts of the United States * * * shall have jurisdiction * * * to restrain violations of [21 U.S.C. 331] * * *.

STATEMENT

Petitioner is a physician who specializes in the treatment of arthritis (Pet. App. 3a). Affidavits submitted by respondents in support of their motion for summary judgment showed that in September 1974, the Food and Drug Administration ("FDA") received information that petitioner had received or was receiving shipments of a dangerous and illegal drug known as Liefcort for use in the treatment of her patients. FDA files indicated that the drug Liefcort is an irrational mixture of potent hormones, and that serious adverse effects have been attributed to the use of the drug.

After a preliminary investigation by FDA's New York District Office indicated that petitioner was distributing the drug involved, a formal inspection[3] of petitioner's premises was ordered.

[3]21 U.S.C. 374(a) authorizes FDA officials, upon presenting appropriate credentials and a written notice to the owner, operator or agent in charge, to enter, at reasonable times, any establishment in which drugs or devices are manufactured, processed, packed or held, for introduction into interstate commerce or after such introduction, and to inspect at reasonable times, and within reasonable limits and in a reasonable manner, such establishment and all pertinent equipment, finished and unfinished materials, containers and labeling in the establishment. Section 374 also provides additional inspection authority with respect to prescription drugs, which extends to records, files, processes and controls; that provision does not apply, however, to practitioners licensed by law to prescribe or administer drugs and who manufacture drugs solely for use in the course of their professional practice.

21 U.S.C. 331(f) makes refusal to permit entry or inspection as authorized by Section 374 a prohibited act.

The district courts of the United States are given jurisdiction by 21 U.S.C. 332, for cause shown, to restrain violations of certain provisions of Section 331, including Section 331(f).

21 U.S.C. 333 provides that any person who violates a provision of 21 U.S.C. 331 shall be imprisoned for not more than one year or fined not more than $1,000, or both, unless certain specified exceptions apply; it also provides additional penalties for second offenses.

On February 10, 1975, Consumer Safety Officer Allen R. Halper visited petitioner's office, presented an official notice of inspection (Pet. App. 32a) to a nurse on duty and explained the purpose of his visit. The nurse advised investigator Halper that Dr. Daley had hours on Wednesday and Thursday from 10:00 a.m. until 4:00 p.m. The nurse declined to provide any information with regard to petitioner's operations or any related information, and she further indicated that all information with respect to Dr. Daley would have to be obtained from her lawyers (Pet. App. 4a).

Thereafter, another inspection was planned for a day on which the nurse indicated Dr. Daley maintained office hours. On February 27, 1975, Consumer Safety Officers John E. Klemmer and Thomas D. Gardine visited petitioner's office to attempt to conduct an inspection. The officers identified themselves to a nurse as FDA investigators, showed their credentials, and issued a notice of inspection (Pet. App. 33a). The inspectors asked to speak to Dr. Daley, but the nurse refused to allow them to enter the reception area. She advised the officers that Dr. Daley was not in the office that day and indicated that they would have to speak to the doctor's attorneys (Pet. App. 4a).

On February 28, 1975, the day following the second attempted inspection, petitioner brought this action seeking broad relief as follows: (1) a declaration that FDA lacks authority and jurisdiction to investigate, inspect, "or otherwise enforce" the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, *et seq.*, against her for her conduct in preparing, prescribing and administering approved drugs or combinations thereof in the course of her medical practice; and (2) an injunction restraining respondents from investigating, inspecting, or otherwise enforcing the provisions of the Act against her for such conduct (Pet. 8-9).

The district court characterized the complaint as aimed at preventing FDA from any further attempts to conduct inspections of Dr. Daley's office (Pet. App. 9a). It concluded that a controversy sufficiently ripe for adjudication did not exist between the parties, and granted respondent's motion for summary judgment dismissing the complaint (Pet. App. 17a-18a).

In reaching its decision, the court applied the guidelines set forth in *Abbott Laboratories* v. *Gardner*, 387 U.S. 136. It noted that *Abbott Laboratories* set forth a two-part test for determining if pre-enforcement relief from agency action should be given. The test requires the "evaluation of 'both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.' " The first portion of the test itself consists of two parts: whether the issues raised are purely legal in nature and whether the challenged agency action is final (Pet. App. 12a).

The district court noted that the only action taken by FDA had been to serve two notices of inspection, and concluded that while the issue raised appeared to be purely legal—that is, FDA's authority under 21 U.S.C. 374(a) to inspect a physician's office—there was no final action upon whose legality the court could pass. The court noted that no inspection had been conducted, and that it was reluctant to anticipate what future action, if any, FDA might take.

The district court also considered the hardship to the parties of withholding court consideration, and determined that the present case was distinguishable on its facts from *Abbott Laboratories*. Specifically, it found that petitioner in the present case, unlike petitioners in *Abbott Laboratories*, was not required to take any positive action to comply with FDA regulations since "the ball, so to speak, is in FDA's court" (Pet. App. 14a). Further, equitable relief was not needed because, if FDA sought to enjoin

petitioner's refusal to permit inspection, petitioner would have an opportunity at that time to justify her refusal. Alternatively, if a criminal proceeding were brought under 21 U.S.C. 333(a) for refusal to permit inspection, petitioner could raise FDA's lack of authority to conduct the inspection as a defense. The court disposed of petitioner's contention that she should not be required to test FDA's authority in a criminal proceeding, using two lines of reasoning. First, it held that there was no indication that FDA intended to prosecute petitioner for refusals to permit FDA inspection; second, it noted that courts have held in parallel situations that good-faith non-compliance, occurring while issues of governmental authority to issue administrative summonses are being disputed, cannot serve as a basis for prosecution (Pet. App. 15a-17a).

The court of appeals affirmed (Pet. App. 1a-6a), stating that it agreed with the district court that there does not yet exist a sufficient case or controversy on which to found declaratory or injunctive relief. Noting that FDA had done no more than to appear on two occasions and request permission to inspect, the court concluded that it was impossible to predict which of a number of possible future actions FDA would take, if any. It reviewed the prerequisites for relief set forth in *Abbott Laboratories* and its companion cases,[4] and concluded "all that appellant here suffers is the tentative possibility of a future inspection." The requirement that the need for equitable relief be "more than remote or speculative" had not, it held, been met (Pet. App. 5a-6a).

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[4] *Toilet Goods Assn.* v. *Gardner*, 387 U.S. 158; *Gardner* v. *Toilet Goods Assn.*, 387 U.S. 167.

ARGUMENT

Petitioner contends (Pet. 27-52) that an actual controversy exists between the parties, and that the courts below erred in applying the standards set forth in *Abbott Laboratories* for determining whether agency action is ripe for judicial review. She urges that the district court should proceed to determine her claim for declaratory and injunctive relief to prevent FDA from any further attempts to conduct, pursuant to 21 U.S.C. 374(a), an inspection of her office.

Petitioner argues that the issue for resolution here is purely a legal one, and that final agency action has taken place. This final agency action consists of FDA's interpretation of its Section 374 inspection authority, as well as its attempts to inspect petitioner's offices. Petitioner further argues that she suffers harm from this agency action because of the possibility of criminal prosecutions both for refusing future inspection and for having refused past inspections. Alternatively, she would suffer injury to her reputation if FDA brought civil proceedings, pursuant to 21 U.S.C. 332, to require petitioner to permit inspection. Petitioner urges that the fact that FDA has conducted two inspections requires the conclusion that further inspections will be conducted (Pet. 46-52).

The court of appeals was, we submit, correct in concluding that declaratory and injunctive relief should be denied because the need for relief has not been shown to be "more than remote or speculative."

1. Declaratory and injunctive relief are not appropriate if the injury claimed is remote or conjectural. *Golden* v. *Zwickler*, 394 U.S. 103, 109-110; *Public Service Commission* v. *Wycoff Co.*, 344 U.S. 237, 240-241; *Maryland Casualty Co.* v. *Pacific Coal & Oil Co.*, 312 U.S. 270.

Petitioner's argument concerning her claimed injury involves a series of speculative assumptions that demonstrate the remoteness of her claim.

She contends that the undisputed fact of attempted inspections shows that FDA will again attempt an inspection. While past FDA behavior may bear on the likelihood of future conduct, petitioner, to support her claim for relief, must nonetheless show that there exists "some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive." *United States* v. *W.T. Grant Co.*, 345 U.S. 629, 633. In the present case, FDA may well decide that, because of enforcement priorities, or because of further information obtained about petitioner or the drug Liefcort, or for other reasons, no further inspections are appropriate. As of this date, no further inspections have in fact been attempted. There is, therefore, only a "mere possibility" of future attempted inspections.

It should be noted that for Dr. Daley to be charged under 21 U.S.C. 331(f) with "refusal to permit entry or inspections as authorized by [21 U.S.C. 374]," FDA at a minimum would have to obtain a refusal from someone more clearly authorized to give the refusal on petitioner's behalf than the nurse who met FDA inspectors at the door of the office on February 10 and February 27, 1975. Further, FDA has routinely obtained an inspection warrant or a search warrant from a magistrate or district court before taking any further enforcement action with respect to a refusal of inspection. None of these events has taken place in this case.

Petitioner argues not only that the Court should assume that FDA officials will attempt future inspections, but that FDA will then take further action concerning the refused inspection that will injure petitioner. This line of argument involves the Court in further speculation. If petitioner

formally refused inspection, FDA would have several courses of action open to it. It could take no further action, it could attempt to negotiate a form of inspection agreeable to both FDA and petitioner, it could obtain and then seek enforcement of a warrant, it could ask the Department of Justice to seek injunctive relief against petitioner under 21 U.S.C. 332, or it could refer the matter to the Department of Justice with a recommendation that criminal proceedings under 21 U.S.C. 333 be brought (see Pet. App. 5a).

The first two courses of action would, of course, cause no injury to petitioner.

In the event that FDA sought an injunction under 21 U.S.C. 332 or sought to enforce a warrant, petitioner could raise her claims concerning FDA's lack of inspection authority as a defense. An adequate remedy at law is therefore available to petitioner to raise her claims, and injunctive relief for petitioner is inappropriate to the extent that it is based on a theory of harm to petitioner resulting from FDA civil enforcement of its inspection authority. It is hardly credible, in any event, that her reputation would be harmed, as she claims, by an FDA civil action against her, since the sole issue would be, in all likelihood, FDA's authority to inspect a physician's offices, not her method of conducting her practice.

FDA, as petitioner notes, could also bring a criminal action for any future[5] refusals to permit inspection, pursuant to 21 U.S.C. 333. It is pure speculation, however,

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[5]Petitioner also appears to have requested declaratory and injunctive relief from FDA actions relating to past refusals of inspection. Equitable relief is clearly inappropriate for this purpose, since petitioner suffers no harm from awaiting resolution of the legality of the past refusals in the context of an action by the government pursuant to 21 U.S.C. 332 or 333. Cf. *Federal Trade Commission* v. *Claire Furnace Co.*, 274 U.S. 160. See also discussion in *Younger* v. *Harris*, 401 U.S. 37, 43-44.

that FDA would choose, and the Department of Justice would approve, this method unless FDA had first attempted enforcement of a warrant or other civil remedies. Moreover, this Court has held that in actions for declaratory or injunctive relief with respect to future criminal prosecutions, plaintiff must demonstrate a "genuine threat" of prosecution. *Ellis* v. *Dyson*, 421 U.S. 426, 434-435; *Steffel* v. *Thompson*, 415 U.S. 452, 458-460; *id.* at 475-476 (Mr. Justice Stewart, joined by Mr. Chief Justice Burger, concurring). In the absence of such a threat, there is no case or controversy; mere fear of prosecution is not sufficient. *Ellis* v. *Dyson*, *supra*, 421 U.S. at 434-435. In this case, petitioner has failed to demonstrate that FDA has threatened her with criminal prosecution; her amended complaint states only that criminal prosecution is "possible" (Pet. App. 28a).

The district court therefore did not abuse its discretion in determining, on these facts, that the agency action had not reached a sufficiently definite form, and that petitioner's claim of harm was not sufficiently definite or immediate to warrant the granting of relief.

2. Petitioner relies upon *Abbott Laboratories*, *supra*, to support her claims. In that case, the agency action challenged was a regulation that had "a direct effect on the day-to-day business of all prescription drug companies * * * . * * * 'Either they must comply with the every time requirement [*i.e.*, the requirement that the established name of the drug accompany the proprietary name every time it appeared] and incur the costs of changing over their promotional material and labeling or they must follow their present course and risk prosecution.' " 387 U.S. at 152 (footnote omitted). Harm to petitioners as a result of withholding of judicial review was therefore shown. In the present case, by contrast, there is no requirement that

petitioner take any action in the absence of further action by FDA, and petitioner has not established the likelihood of such action.

The present case differs significantly from *Gardner* v. *Toilet Goods Assn.*, 387 U.S. 167, upon which petitioner also relies.[6] That case, like *Abbott Laboratories,* involved FDA regulations that were "self-executing, and [had] an immediate and substantial impact upon the respondents." 387 U.S. at 171. Failure to comply with the regulations carried substantial penalties. Unlike the present case, therefore, *Gardner* involved agency action requiring immediate

[6]Two additional cases cited by petitioner in support of her position (Pet. 36) are distinguishable since they involved agency action that had an immediate impact on plaintiffs' business and required affirmative action by plaintiffs. In *Independent Broker-Dealers' Trade Association* v. *Securities & Exchange Commission,* 442 F. 2d 132 (C.A. D.C.), certiorari denied, 404 U.S. 828, the court held reviewable an SEC "request" to the New York Stock Exchange that caused the exchange to abolish a form of commission formerly paid to plaintiffs. In *National Automatic Laundry and Cleaning Council* v. *Shultz,* 443 F. 2d 689 (C.A. D.C.), the court held ripe for review a letter of the Wage-Hour Administrator stating that the Fair Labor Standards Act applied to the council's thousands of members; failure to comply with this agency interpretation could have subjected companies to double damages, and in extreme cases to criminal liability.

The case is also distinguishable from *Doe* v. *Bolton,* 410 U.S. 179, cited by petitioner (Pet. 42). In that case the immediate impact of the abortion statute was to force the physician not to perform abortions which they would otherwise perform, unless they were willing to risk prosecution. In the present case, it is not clear that FDA will ever attempt another inspection or that, if it does, petitioner's refusal to comply will result in criminal sanctions; there is no present constraint on petitioner and no "direct threat of personal detriment." 410 U.S. at 188.

affirmative action by petitioners and imposing penalties for failure to take the action.[7]

3. The decision of the Court of Appeals for the Seventh Circuit in *Durovic* v. *Palmer,* 342 F. 2d 634, certiorari denied, 382 U.S. 820, is in agreement with the decision below. In *Durovic* the court refused to grant an injunction against future inspections similar to those of which petitioner complains here. See also *American Dietaids Co.* v. *Celebrezze,* 317 F. 2d 658 (C.A. 2), certiorari denied, 375 U.S. 896 (denying an injunction against certain methods of inspection in absence of showing of intention or threat to carry out additional inspections).

4. Since the court of appeals correctly held that petitioner's complaint is not ripe for review, there is no need to consider petitioner's argument (Pet. 52-60) that 21 U.S.C. 374(a) does not apply to inspections of physicians' offices, even for purposes of examining equipment and finished and

[7]The present case has more similarities with the agency action found not to be ripe for review in *Toilet Goods Assn.* v. *Gardner,* 387 U.S. 158. In that case this Court found that final regulations relating to color additives that set forth penalties for failure to permit inspection by FDA were not an appropriate subject for judicial review, in the absence of attempted enforcement by FDA. This Court noted that "[a]t this juncture we have no idea whether or when such an inspection will be ordered and what reasons the Commissioner will give to justify his order. * * * This is not a situation in which primary conduct is affected—when contracts must be negotiated, ingredients tested or substituted, or special records compiled. * * * [N]o advance action is required of cosmetics manufacturers * * *." *Id.* at 163-164.

Similarly, in this case, FDA has given no indication that inspection will be ordered or on what facts it would base its authority to carry out the inspection. "Primary conduct" of petitioner is not affected, since no advance preparation is required of petitioner.

unfinished materials.[8] This issue, even if ripe for judicial review, is not properly presented to this Court since it was not considered by the courts below.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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FEBRUARY 1977.

[8] In any event, the exception for practitioners to which petitioner refers applies only to the special authority contained in the second sentence of Section 374(a), dealing with inspections relating only to prescription drugs. The general inspection authority contained in the first sentence of Section 374(a) is not affected by the exception.